

COVID-19 Vaccine Indications for Patients Who Are Immunocompromised

Effective August 13, 2021, the Centers for Disease Control and Prevention (CDC) [recommends](#) that people who are moderately to severely immunocompromised receive an additional dose of an mRNA COVID-19 Vaccine (Pfizer-BioNTech or Moderna) at least 28 days after the completion of the initial mRNA COVID-19 vaccine series.



Patient Education Resources:

- [COVID-19 Vaccines for Moderately to Severely Immunocompromised People](#)
- [How to Talk with Patients Who Are Immunocompromised](#)

Frequently Asked Questions for Healthcare Providers

Who is currently recommended to receive an additional mRNA COVID-19 vaccine dose following a 2-dose primary mRNA COVID-19 vaccine series?

Consider giving patients an additional mRNA COVID-19 vaccine dose if they are aged 12 years and older and have moderate to severe immune compromise (from a medical condition or treatment).

Some of the conditions and treatments that result in immunosuppression include, but are not limited to, the following:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥ 20 mg prednisone or equivalent per day when administered for ≥ 2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

When assessing a patient's level of immune compromise, consider disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment.

In certain situations, a patient's primary healthcare provider, possibly in consultation with other specialists, is best positioned to determine their patient's level of immunocompromise.



Additional information about the level of immune suppression associated with a range of medical conditions and treatments can be found in:

- [General best practices for vaccination of people with altered immunocompetence](#)
- [CDC Yellow Book](#)
- [Infectious Diseases Society of America policy statement, 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host](#) [↗](#)

My practice serves many dialysis patients. Should dialysis patients receive an additional mRNA COVID-19 vaccine dose to supplement a 2-dose primary mRNA COVID-19 vaccine series?

CDC recommends an additional mRNA vaccine dose for dialysis patients who are moderately to severely immunocompromised (from a medical condition, medication, or treatments). Treatment with hemodialysis, on its own, may not result in moderate to severe immune compromise.

[Data from several studies](#) suggest that the vast majority of dialysis patients develop an immune response after receiving a 2-dose primary mRNA COVID-19 vaccine series. An additional dose is not recommended for immunocompetent dialysis patients.

Some dialysis patients have health conditions or take medications that may result in moderate to severe immune compromise. For example, a dialysis patient awaiting organ transplantation or who is post-organ transplant may be immunocompromised. The patient's clinical team can assess the degree of altered immunocompetence and whether the patient should receive an additional dose of mRNA COVID-19 vaccine.



Additional Information:

- [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States](#)

Should pregnant patients receive an additional mRNA COVID-19 vaccine dose to supplement a 2-dose primary mRNA COVID-19 vaccine series?

CDC recommends an additional mRNA vaccine dose for pregnant people who are moderately to severely immunocompromised (from a medical condition, medication, or treatment).

Pregnancy impacts some aspects of the immune system but is not typically associated with moderate to severe immunocompromise. Generally, pregnant people mount an adequate immune response to the primary mRNA COVID-19 vaccine series. An additional dose is not recommended for immunocompetent pregnant people.

Some pregnant people may have health conditions or take medications that result in moderate to severe immunocompromise. The patient's clinical team can assess the degree of altered immunocompetence and whether the patient should get an additional dose of mRNA COVID-19 vaccine.



Additional Information:

- [COVID-19 Vaccines While Pregnant or Breastfeeding](#)
- [New CDC Data: COVID-19 Vaccination Safe for Pregnant People](#)

Should patients with HIV infection receive an additional mRNA COVID-19 vaccine dose to supplement a 2-dose primary mRNA COVID-19 vaccine series?

[CDC recommends](#) an additional mRNA vaccine for patients with advanced or untreated HIV infection.



Immunosuppression in Patients with HIV Infection Defined:


Chapter 5 of [CDC's Yellow Book](#) defines severe immunosuppression in patients with HIV infection as having:

- CD4 cell counts less than 200/mm³
- A history of an [AIDS-defining illness](#) without immune reconstitution
- Clinical manifestations of symptomatic HIV infection

Why does CDC recommend that people who are immunocompromised receive an additional mRNA COVID-19 vaccine dose to supplement a 2-dose primary mRNA COVID-19 vaccine series?

People with immunocompromising conditions or people who take immunosuppressive therapies are [at increased risk for severe COVID-19](#) illness.

[Studies](#) have found evidence of reduced immune response to a 2-dose primary mRNA COVID-19 vaccine series in some groups of immunocompromised people. People who are immunocompromised also may have a higher rate of breakthrough SARS-CoV-2 infections than the general population.

[Small studies](#)  have demonstrated that an additional mRNA COVID-19 vaccine dose may enhance antibody response in some immunocompromised people who received a 2-dose primary mRNA COVID-19 vaccine series.

Although the clinical benefit of an additional dose of mRNA COVID-19 vaccine in immunocompromised people who received a primary mRNA COVID-19 vaccine series is not precisely known, the potential to increase immune response, coupled with an acceptable safety profile, supports the use of an additional mRNA COVID-19 vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series in this population.

Is an additional dose the same as a booster dose?

There are two distinct possible ways an additional vaccine dose can be used.

- An **additional dose** of mRNA COVID-19 vaccine associated with a primary vaccine series is recommended when the initial immune response following a primary mRNA COVID-19 vaccine series is likely to be insufficient. In other words, the additional dose augments the primary series.

[Studies](#) indicate some immunocompromised people do not always build as high a level of immunity after vaccination as immunocompetent people do. An additional dose may prevent serious and possibly life-threatening COVID-19 in people whose immune system may not have fully responded to their initial 2-dose vaccine series.

- A **booster dose** of vaccine is administered when the initial immune response to a primary vaccine series is likely to have waned over time. In other words, although an adequate immune response occurred after the primary vaccine series, over time, immunity decreases.

After a thorough review of the evidence, the [Advisory Committee on Immunization Practices \(ACIP\)](#), composed of medical and public health experts, who develop recommendations and provide guidance to the CDC Director on the use of vaccines, will make recommendations on the use of boosters for the public.

On August 18, 2021, the U.S. Department of Health and Human Services (HHS) announced [an operational plan for booster dose administration](#)  beginning the week of September 20, 2021.

This plan is subject to FDA conducting an independent evaluation and determination of the safety and effectiveness of a third dose of the Pfizer-BioNTech and Moderna mRNA vaccines and ACIP issuing booster dose recommendations based on a thorough review of the evidence.

A person is asking for an additional dose of mRNA COVID-19 vaccine. How do I know if they are moderately to severely immunocompromised?

Individuals can self-attest to their moderately to severely immunocompromised status and receive the additional dose wherever vaccines are offered. Vaccinators should not deny COVID-19 vaccination to a person due to lack of documentation. This will help prevent barriers to access for this vulnerable population receiving a needed additional dose.

[If people who are immunocompromised have questions about the additional dose](#), they should discuss with their healthcare provider whether getting an additional dose is appropriate for them.

CDC is providing further information regarding vaccine administration to immunocompromised individuals to states, pharmacies, health centers, and all vaccine providers.

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Should my immunocompromised patient have an antibody test to determine whether they need an additional dose? —

No. FDA and CDC do not recommend using serologic or cellular immune testing to assess immune response to vaccination or to determine if someone needs an additional dose. The [utility of serologic testing](#) or cellular immune testing to assess immune response to vaccination has not been established.

What is the recommended dosage for the additional mRNA COVID-19 vaccine dose to supplement a primary 2-dose mRNA COVID-19 vaccine primary series? —

The dosage for the additional dose is identical to the dosage for the 2-dose primary vaccine series

- Moderna COVID-19 Vaccine: 0.5 mL
- Pfizer-BioNTech COVID-19 Vaccine: 0.3 mL

Is there a preferred vaccine product for the additional dose? —

No. CDC does not express a product preference; however, you should administer the same product as the initial 2-dose mRNA COVID-19 primary vaccine series (Pfizer-BioNTech if at least 12 years old or Moderna if at least 18 years old).

If the mRNA COVID-19 vaccine product given for the first two doses is not available, administer the other mRNA COVID-19 vaccine product. Do not administer more than 3 mRNA COVID-19 vaccine doses.

What is the recommended interval between a 2-dose primary mRNA COVID-19 vaccine series and an additional dose to supplement a primary vaccine series? —

CDC recommends at least 28 days between administration of the second dose of the 2-dose mRNA COVID-19 vaccine primary series and an additional dose. However, both the nature of immunosuppression and optimization of the patient's medical condition and response to vaccine should be considered. A patient's clinical team is best situated to determine the degree of immune compromise and appropriate timing of vaccination.

My immunocompromised patient received their 2-dose primary mRNA COVID-19 vaccine series several months ago. Is there a maximum interval after which the additional dose to supplement the primary vaccine series should not be administered? —

No. There is no maximum interval. If it has been longer than 28 days since a patient received the second dose of their 2-dose primary mRNA COVID-19 vaccine series, administer an additional dose at the next opportunity. Do not restart the series.

Does the 4-day grace period apply to the 28-day interval for the additional dose? —

Yes. Schedule the additional dose at least 28 days after the second dose in the 2-dose primary mRNA COVID-19 vaccine series; however, an additional dose administered up to 4 days before the recommended date (4-day grace period) are considered valid. This means when reviewing records, an additional dose of Moderna or Pfizer-BioNTech COVID-19 Vaccine administered 24 or more days after the second dose is considered valid.

My immunocompromised patient received a mixed 2-dose primary mRNA COVID-19 vaccine series. Which mRNA COVID-19 vaccine is preferred for the additional dose? —

Patients who have previously received a mixed 2-dose primary series may receive either Moderna or Pfizer-BioNTech COVID-19 Vaccine for the additional dose. Do not administer more than 3 mRNA COVID-19 vaccine doses to a patient.

What should we do for immunocompromised patients who previously received Janssen COVID-19 Vaccine? Should we administer an additional dose of COVID-19 vaccine? —

At this time, CDC does not recommend any additional doses of any COVID-19 vaccine for people who received 1 dose of the Janssen (Johnson & Johnson) COVID-19 Vaccine.

Currently, there are not enough data to support the use of an additional mRNA COVID-19 vaccine dose after a single-dose Janssen COVID-19 vaccination series in immunocompromised people.

FDA and CDC are actively working to provide guidance on this issue.

My immunocompromised patient received 1 dose of mRNA COVID-19 vaccine followed by 1 dose of Janssen COVID-19 Vaccine in error. Should I administer an additional dose of mRNA COVID-19 vaccine?

No. Currently there are insufficient data to support the use of an additional mRNA COVID-19 vaccine dose after Janssen COVID-19 vaccination in immunocompromised people.

FDA and CDC are actively working to provide guidance on this issue.

Are moderately to severely immunocompromised people who received 1 dose of Janssen or 2 doses of mRNA COVID-19 vaccine still considered fully vaccinated?

Yes. Immunocompromised patients who have completed a primary vaccine series (i.e., 2-dose mRNA vaccine series [Pfizer-BioNTech or Moderna] or a single dose of the Janssen vaccine) are considered [fully vaccinated](#) 2 weeks after completion of the series. However, CDC recommends an additional dose of an mRNA COVID-19 vaccine after an initial 2-dose primary mRNA COVID-19 vaccine series for people with moderate to severe immune compromise from a medical condition or treatments (aged 12 years and older for Pfizer-BioNTech or aged 18 years and older for Moderna). The additional dose will help improve their immune response to their primary vaccine series.

Fully vaccinated patients who are moderately to severely immunocompromised should continue to follow [current prevention measures](#) (including [wearing a mask](#), [staying 6 feet apart](#) from others they don't live with, and avoiding crowds and poorly ventilated indoor spaces) to protect themselves against COVID-19 until advised otherwise by their healthcare professional.

Are there special considerations for timing immunosuppressive therapy with administration of COVID-19 vaccines?

Whenever possible, complete mRNA COVID-19 vaccination doses (including the primary 2-dose series and the additional dose) at least 2 weeks before initiating or resuming immunosuppressive therapies.

Timing of COVID-19 vaccination should take into consideration current or planned immunosuppressive therapies and optimization of both the patient's medical condition and response to vaccine.

When it is not possible to administer a complete COVID-19 vaccine series (i.e., 2 doses of mRNA COVID-19 vaccine or a single dose of Janssen COVID-19 Vaccine) in advance, you may still vaccinate patients who are receiving immunosuppressive therapy.

Decisions to delay immunosuppressive therapy to complete COVID-19 vaccination should consider the patient's risks related to their underlying condition. Also, certain patient populations (e.g., bone marrow transplant patients post ablative therapy) may warrant additional unique considerations. The patient's clinical team is best situated to determine the degree of immune compromise and appropriate timing of vaccination.

Do I give the patient a new vaccination record card for their additional dose?

All vaccine recipients should have received a CDC vaccination card when they were initially vaccinated.

When scheduling appointments, remind patients to bring their vaccination card. If patients do not bring their card, make every effort to verify vaccination history.

- If patients bring their vaccination card: Document the additional dose on their existing card. There are two additional spaces on the card.
- If patients are unable to locate or do not bring their vaccination card: Provide a new card to record the additional dose.

If an immunocompromised patient is infected with SARS-CoV-2 after receiving 2 doses of mRNA COVID-19 vaccine, should they still receive the additional dose to supplement the primary series?

Yes. CDC recommends individuals receive all recommended vaccines [regardless of prior SARS-CoV-2 infection](#). The timing of when a person receives the additional dose may be affected by their COVID-19 illness or treatment.

- **People with a current infection:** Defer vaccination of people with known current SARS-CoV-2 infection until the person has recovered from acute illness (if the person has symptoms) and until [criteria](#) have been met for them to discontinue isolation. This recommendation applies to any vaccine, including the first and second doses of COVID-19 vaccine.
- **People who previously received passive antibody therapy as part of COVID-19 treatment:** Defer vaccination for at least 90 days after receipt of passive antibody therapy (monoclonal antibodies or convalescent plasma). This recommendation applies to people who receive passive antibody therapy
 - Before receiving any COVID-19 vaccine dose
 - After the first dose of mRNA COVID-19 vaccine but before the second dose
 - After the second dose of mRNA COVID-19 vaccine but before the additional (i.e., third) dose



Additional Information:

- [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States](#)

Are booster doses recommended for the general public?

After a thorough review of the evidence, the Advisory Committee on Immunization Practices (ACIP), composed of medical and public health experts, who develop recommendations and provide guidance to the CDC Director on the use of vaccines, will make recommendations on the use of boosters for the public.

On August 18, 2021, the U.S. Department of Health and Human Services (HHS) announced [an operational plan for booster dose administration](#) [↗](#) beginning the week of September 20, 2021.

This plan is subject to FDA conducting an independent evaluation and determination of the safety and effectiveness of a third dose of the Pfizer-BioNTech and Moderna mRNA vaccines and ACIP issuing booster dose recommendations based on a thorough review of the evidence.

How do I bill for administering COVID-19 vaccines?

If you administer additional vaccine doses on or after August 12, 2021, consistent with the FDA's updated emergency use authorizations, acknowledge and document (e.g., in the medical record) your patient's self-reported qualifying conditions for the additional dose.



Additional Information:

- [Medicare Billing for COVID-19 Vaccine Shot Administration](#) [↗](#)

Where can I find more FAQs for healthcare providers?



Additional COVID-19 Vaccine FAQs for Healthcare Providers:

- [FAQs for Private and Public Healthcare Providers About Implementing the CDC COVID-19 Vaccination Program in Provider Practices](#)
- [COVID-19 Vaccine FAQs for Healthcare Professionals](#)

- [COVID-19 vaccine FAQs for healthcare professionals](#)
- [Janssen COVID-19 Vaccine \(Johnson & Johnson\) Questions](#)
- [Moderna COVID-19 Vaccine Questions](#)
- [Pfizer-BioNTech COVID-19 Vaccine](#)

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